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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,987	03/20/2001	Joseph P. Loeffler	016770-004500US	1516

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/19/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,987

Applicant(s)

LOEFFLER ET AL. *cl*

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-44 and 50-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37-44 and 50-69 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13 6) ☐ Other:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 63-64 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Openings are open by inherent definition, thus to set forth the operation of the device in terms of opening the opening means additional structure exists that is unclaimed and that there are no openings. As currently claimed the device is inoperable because it requires some sort of sealed/sealing structure that is within which an opening is formed during operation and not before as claimed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 55-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 55 recites the limitation "the receiving portion" in line 5. There is insufficient antecedent basis for this limitation in the claim.

4. In regards to claim 63-64, the claim language does not make logical sense, applicant sets forth an ampoule with an opening and then proceeds to describe what happens when the "opening" is "opened" openings are inherently open, that is the nature of an opening.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 55-56, 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Bepak (WO94/09912).

In regards to claim 55, Bepak discloses an aerosolization device (any fig) for delivery of a liquid medicament to a patient's respiratory system comprising a receiving member configured to receive an ampoule containing a liquid medicament (fig 6, 14, note the channel wherein ampoules 71 reside) and an aerosol generator (2-13 & 17-18) in fluid communication with the receiving member and configured to receive at least some liquid medicament from the receiving member (17-18), and to aerosolize the liquid medicament received from the receiving member (see blow ups of fig 1-2), the aerosol generator comprising an aperture plate having a plurality of apertures (6) and a vibratable element (transducer 10) that is mechanically linked to the aperture plate such that vibration of the vibratable element causes the aperture plate to vibrate, thereby ejecting droplets of liquid medicament.

In regards to claim 56, Bepak discloses the vibratory element comprising a piezoelectric transducer (10) wherein the aerosol generator is further comprised of control circuitry (oscillatory circuit 11 page 5 lines 30-33) for sending an electrical signal to the piezoelectric transducer thereby causing the transducer to vibrate.

In regards to claims 61 & 62, Bepack discloses the device comprising an ampoule configured to be coupled to the receiving member, the ampoule containing liquid medicament. (71 sized shaped & designed to be coupled to 14 by dint of insertability in to the channel of 14)

In regards to claim 63, Bepak discloses an ampoule comprising a first opening (note spent ampoules to your right when viewing fig 6) such that when the first opening is open the liquid medicament is exposed to the aerosol generator.

In regards to claim 64, Bepak is fully capable of forming a second opening in the ampoule (note plunger 74) which when formed would assist in allowing medicament to flow toward the aerosol generator.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 37-44 & 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bepak in view of Ivri (US 5758637).

In regards to claim 57, Bepak substantially discloses the instant application's claimed invention, but does not explicitly disclose use of tapered holes. However, Ivri disclose such (col. 11, line 25). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to

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have taken the features of Ivri and used them with the device of Bespak. The suggestion/motivation for doing so would have been to optimize aerosolization of medicament. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 58, the suggested device discloses the plate have a front & rear face and the tapering narrowing from the rear to front face (See col. 11 lines 20-30 of Ivri).

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 59, the suggested device discloses the apertures being within the range of 1-6 microns (see bespack page 5, line 22).

In regards to claim 60, Bespack substantially discloses the instant application's claimed invention, but does not explicitly disclose the plate having a non-planar geometry. However, Ivri disclose such (see plate 26). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary

skill in the art to have taken the features of Ivri and used them with the device of Bespack. The suggestion/motivation for doing so would have been to optimize delivery of medicament to the user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 65, the suggested device of Bespack & Ivri discloses the instantly claimed invention as set forth in the rejection of claims 55, 57-58, 60-64 which is herein incorporated by reference as the rejection to claim 65.

5. Claims 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bespack & Ivri as applied to claim 65 above, and further in view of Singier (US 3325031).

In regards to claim 66, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a tab to cover or seal the first opening prior to use. However, Singier disclose such (23 & 35). The references are analogous since they are from the same field of endeavor, the ampoule arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Singier and used them with the suggested device. The suggestion/motivation for doing so would have been to insure more precise and controlled opening of the ampoule. Therefore it would

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have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 67, the suggested device discloses the capability of having a second hole to assist in the flow of medicament from the ampoule

In regards to claim 68, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a second tab to cover or seal the first opening prior to use. However, Singier disclose such (23 & 35). The references are analogous since they are from the same field of endeavor, the ampoule arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Singier and used them with the suggested device. The suggestion/motivation for doing so would have been to insure more precise and controlled opening of the ampoule. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 69, the suggested device discloses the apertures being within the range of 1-6 microns (see bespack page 5, line 22).

In regards to method claims 37-44 & 50-54, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 55-69.

Response to Arguments

6. Applicant's arguments with respect to claims 37-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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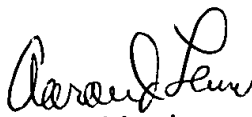
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6085740, 5586550, 5297734, 5152456, 4465234
EPO 0682570; GB 2272389; WO 93/10910

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


J. Weiss
11/7/03


Aaron J. Lewis
Primary Examiner